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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/847,042 | 05/01/2001 | Michael R. Leadbetter | P-088-R | 5218 |

27038 7590 10/16/2002

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EXAMINER

RUSSEL, JEFFREY E

| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 10/16/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,042

Applicant(s)

LEADBETTER ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 14, 16, 19 and 23-31 is/are rejected.
- 7) ☒ Claim(s) 9, 11-13, 15, 17, 18, and 20-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Claims 3, 4, 29, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the R-terminus" in claims 3 and 29 because there is no previous indication that the glycopeptides comprise a resorcinol ring and because glycopeptides do not inherently comprise a resorcinol ring. At claim 31, line 3, some part of the dependency is missing from the claim.
2. Claims 5-7, 19, 23-27, 30, and 31 are objected to because of the following informalities: At claim 5, page 83, lines 3 and 13, "to" should be inserted before "form". At claim 19, line 12, the beginning bracket does not match the end parenthesis found in the first chemical formula. Appropriate correction is required.
3. Instant claims 1-4, 14-16, 19-22, 28, and 29 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/213,410 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed subject matter.

Instant claims 5-13, 17, 18, 23-27, 30, and 31 are deemed not to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/213,410 because the provisional application, under the test of 35 U.S.C. 112, first paragraph does not disclose that R^4 and R^5 can be joined to form a heterocyclic ring (see claim 5); does not disclose that R^6 can be a saccharide group substituted with the second or third groups (see claim 5); does not disclose that R^{12} can be the group at page 84, line 10; does not disclose the R^3 groups of claims 11 and 17; does not disclose the R^5 groups of claims 12 and 18; does not disclose the amounts of

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hydroxypropyl- β -cyclodextrin recited in claim 26; and does not disclose the ratios recited in claim 27.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

5. Claims 5-8, 10, 23, 30, and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by the WO Patent Application 00/39156. The WO Patent Application '156 teaches compound 144 (see pages 19 and 30) which comprises a phosphonate at a position corresponding to Applicants' R³ substituent. The compound is used in pharmaceutical compositions in combination with pharmaceutically acceptable carriers for treating infectious diseases, especially those caused by Gram-positive microorganisms. Administration can be parenteral. See, e.g., page 92, lines 5-10; page 94, lines 3-17; and page 99, lines 11-26.

6. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 00/39156 as applied against claims 5-8, 10, 23, 30, and 31 above, and further in view of Bodor (U.S. Patent No. 4,983,586). The WO Patent Application '156 does not teach combining its compound with a hydroxypropyl- β -cyclodextrin carrier. Bodor teaches that aqueous parenteral solutions of drugs which are insoluble or only sparingly insoluble in water and/or which are unstable in water can be combined with hydroxypropyl- β -cyclodextrin. The drugs include antibacterials/antibiotics. See, e.g., the Abstract and column 14, line 62. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made

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to include the hydroxypropyl- β -cyclodextrin of Bodor in the aqueous solutions of the compound of the WO Patent Application '156 because the hydroxypropyl- β -cyclodextrin would have been expected to improve the solubility and/or stability of the compound of the WO Patent Application '156. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal amounts and proportions of the compound of the WO Patent Application '156 and the hydroxypropyl- β -cyclodextrin of Bodor because dosage and component ratio are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

7. Claims 1, 2, 5-8, 10, 14, 16, 19, 23, 28, 30, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Judice et al (U.S. Patent No. 6,392,012). Judice et al is the U.S. equivalent of the WO Patent Application 00/39156 applied above, and anticipates the claims for the same reasons set forth above. See especially columns 15-16, compound 144.

8. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being obvious over Judice et al (U.S. Patent No. 6,392,012) as applied against claims 1, 2, 5-8, 10, 14, 16, 19, 23, 28, 30, and 31 above, and further in view of Bodor (U.S. Patent No. 4,983,586). Judice et al is the U.S. equivalent of the WO Patent Application 00/39156 applied above, and in combination with Bodor suggests the claims for the same reasons set forth above.

9. Claims 9, 11-13, 15, 17, 18, and 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 3, 4, and 29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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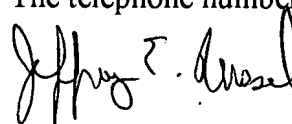
The prior art of record does not teach or suggest glycopeptides substituted with at least one substituent comprising a phosphono group and having the structures recited in instant claims 3, 4, 9, 11-13, 15, 17, 18, and 20-22. With respect to instant claim 29, because the prior art of record does not teach or suggest a glycopeptide substituted at a resorcinol ring with a substituent comprising a phosphono group, the prior art of record also does not teach or suggest a method of synthesizing such a glycopeptide.

Judice et al (U.S. Patent No. 6,392,012) has been carefully considered with respect to issues of obviousness-type double patenting. However, the claims of Judice et al are not deemed to suggest the instant claims for reasons consistent with *In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994). See also MPEP 2144.08.

Jamison et al is cited as art interest, but is not deemed to teach or suggest the instant claimed invention because Jamison et al do not teach or suggest a multi-ring peptide core as required by Applicants' definition of the term "glycopeptide" at page 36, lines 23-25, of the specification.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
October 3, 2002